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| 10/764,619 | 01/26/2004 | Gary McAlister | 10121/00308 | 8922 |

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| EXAMINER |
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ANDERSEN, MICHAEL T

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| ART UNIT | PAPER NUMBER |
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3734

DATE MAILED: 11/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/764,619

Applicant(s)

MCALISTER ET AL.

Examiner

M. Thomas Andersen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 September 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 57-72 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 57-72 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Acknowledgement is made of the response filed 9/26/2006, to the non-final Office action dated 6/14/2006.

Specification

Acknowledgement is made to the amendment of the specification. The objection to the specification is thus withdrawn.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims **57-72** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Mills et al.**, U.S. Patent No. **5,037,021**, in view of **Solar et al.**, U.S. Patent No. **5,947,983**. Both Mills and Solar disclose a surgical stapling apparatus and related methods.

Claim **57**: Mills's figures 5a-5c show a surgical stapling apparatus comprising a housing 200, a distal end cap (left hand side), a window 202, an anvil 260 formed on a first edge of the window, a stapling apparatus (comprising 206, 205, 209) mounted within the housing for movement between a stapling position (fig. 5c) and a tissue receiving position (fig. 5a) in which the staple firing surface 205 is separated from the anvil 260 to open the window 202 and expose a tissue receiving cavity within an interior of the housing 200.

Figure 8 in Mills shows that the stapling apparatus is slidably coupleable to an endoscope 800 for advancement therealong.

The end of the piston 205 is considered the staple firing surface. Once cable 206 is retracted, the staple can be considered to be out of or away from the staple firing surface. Thus, the stapling firing apparatus drives a staple out of the stapling firing surface through tissue in the tissue receiving cavity 202. "Out" is considered to have the typical meaning, viz. away from, or not in, the normal or usual place, position, state, etc. out. Dictionary.com. Dictionary.com Unabridged (v 1.0.1), Based on the Random House Unabridged Dictionary, © Random House, Inc. 2006.

<http://dictionary.reference.com/browse/out> (accessed: November 20, 2006).

In other words, after stapling, the staple is away from the typical position, i.e. the position of the staple before the surgical stapling procedure.

Also, once the cable 206 is retracted, the staple firing surface (end of 205) is "separated from the anvil 260 to open the window and expose a tissue receiving cavity."

Mills does not expressly disclose "a tissue grasping mechanism extendible through the window" but merely discloses a suction channel 204 and suction source for drawing tissue into the window cavity 202. Drawing the tissue into a cavity by means of suction or by means of a tissue grasping mechanism is obvious and well-known in the art. Solar discloses a tissue grasper 160 in figure 3. "Any embodiment of the present invention optionally includes a tissue grasper 160 within the third tube 130, as shown in FIG. 3. As is known in the art, the tissue grasper grabs tissue with, for example, a pair of jaws, 161. Use of the tissue grasper 160 is preferred where the third tube 130 is not a

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vacuum tube. In this situation, the cutting and stitching of tissue or protrusions from body lumen walls occurs by the methods as herein described and illustration, except that the grasped tissue is pulled into the third tube by the tissue grasper 160 rather than by the action of vacuum." Solar, col. 5, lines 24-33. Thus, it would be obvious to use a tissue grasper in place of the vacuum tube 204 in Mills in view of Solar.

Claim 58: Mills's figure 8 shows a control handle (6 and 15) that remains outside the body, and a flexible sheath (800).

Claim 59: It is considered inherent that the flexible sheath has a column strength sufficient to allow an operator to push the housing along an endoscope into a body lumen by pushing the flexible sheath into the body lumen.

Claim 60: As can be seen in Mills's figures 5a-5c, the stapling apparatus is mounted within the housing, and the staple 209 rotates about an axis found in the housing between the stapling (fig. 5c) and tissue receiving positions (fig. 5a).

Claim 61: Part of the stapling apparatus (wire 206 and piston 205) in Mills moves substantially parallel to a longitudinal axis of the housing.

Claim 62: Mills does not expressly disclose a housing with an endoscope receiving lumen including a proximal and distal opening formed in the distal end of the cap. However, positioning a stapling apparatus over an endoscope, and thus having a proximal and distal end opening in the stapling apparatus housing, is old and well known in the art. Solar discloses, "The tubes 110, 120 and 130 are introduced into the body by any suitable means. It is preferred, however, that the device of the present invention be inserted into the body in association with an endoscope (e.g., within a

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working channel of an endoscope or over the exterior surface of an endoscope), which allows for the in-situ identification of diseased tissue. Once the endoscope is positioned to a target location within a body lumen, the device 100 is extended from the endoscope working channel to grasp, cut and remove diseased tissue.” Solar, col. 5, lines 11-20.

It would be obvious to insert an endoscope through the entire housing 200 in Mills so as to better view the stapling procedure.

Claim 63: Mills’s figure 8 shows a control handle (6 and 15) that remains outside the body, and a flexible sheath (800).

Claim 64: Mills does not expressly disclose a tissue cutting mechanism, but Solar discloses a tissue cutting mechanism (figure 1B, numeral 132) very similar to applicant’s that would be beneficial to use in Mills. In view of Solar, it would be obvious to place a tissue cutting mechanism in Mills’s apparatus to remove diseased tissue, as is well-known in the art.

Claim 65: The tissue cutting mechanism (fig. 1B) in Solar includes a partially cylindrical member rotatably mounted within the housing. The tissue cutting blade in Solar is not an angled cutting surface. However, Mills discloses an angled blade 44 for cutting thread. It would be obvious to use an angled blade so as to gradually cut the tissue which results in a more effective cut.

Claim 66: As can be seen in Mills’s figures 5a-5c, the stapling apparatus is mounted within the housing, and the staple 209 rotates about an axis found in the housing between the stapling (fig. 5c) and tissue receiving positions (fig. 5a).

Claim 67: Part of the stapling apparatus (wire 206 and piston 205) in Mills moves substantially parallel to a longitudinal axis of the housing and across the window 202.

Claim 68: Mills discloses a method comprising the steps of endoscopically locating a portion of tissue, sliding a housing along the endoscope to a desired position adjacent to the portion of tissue to be resected, the housing including the structure as described in claim 57 (see discussion above), moving the stapling apparatus to a tissue receiving position, drawing the portion of tissue to be resected into the housing through the window folded over so that two full thicknesses of tissue of a wall of the body lumen are received within the window (figs. 5a-5c); moving the stapling apparatus to the stapling position (fig. 5a – drawing the wire 206 and piston 205 back) clamping the portion of tissue to be resected between the stapling apparatus and the anvil (fig. 5c), driving staples from the stapling apparatus through the two thicknesses of wall tissue to couple the two thicknesses of wall tissue to one another; and (as mentioned above, in view of Solar, it would be obvious to do) cutting tissue radially within the stapled tissue from the stapled tissue. See Mills, col. 5, line 66 – col. 6, line 41; Mills, figs. 5a-5c; Mills, abstract; Solar, figs. 1A-1B.

Claim 69: As mentioned above, part of the stapling apparatus (the staple 209) in Mills is rotated within the housing 200 between the tissue receiving (fig. 5a) and stapling positions (fig. 5c).

Claim 70: As mentioned above, part of the stapling apparatus (wire 206 and piston 205) in Mills is moved longitudinally within the housing between the tissue receiving and stapling positions (figs. 5a-5c).

Claim 71: As mentioned above, figure 8 in Mills discloses a control handle (6 and 15) which remains outside the body by a flexible sheath, and wherein the operative housing 200 is slid along the endoscope by pushing the flexible sheath into the body lumen.

Claim 72: Mills discloses a flexible endoscope 800 (figure 8), a housing 200, a distal end cap (left hand side), a window 202, an anvil formed on a first edge of the window 260, a stapling apparatus (206, 205, 209) mounted within the housing for movement between a stapling position (figure 5c) and a tissue receiving position (figure 5a) in which the staple firing surface 205 is separated from the anvil to open the window 202 and expose a tissue receiving cavity within an interior of the housing 200. Figure 8 in Mills shows that the stapling apparatus is slidably coupleable to an endoscope 800 for advancement therealong.

See claim 57 for a discussion on the "stapling firing surface."

As mentioned above, in view of Solar, it would be obvious to use a tissue grasper in place of the vacuum tube 204 in Mills.

Response to Amendments

Applicant's arguments filed 9/26/2006 have been fully considered but they are not persuasive. As explained above in regard to claim 57, the staple 209 is driven out of a staple firing surface moveable between a stapling position adjacent to an anvil and a tissue receiving position "separated from the anvil to open the window and expose a tissue receiving cavity.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to M. Thomas Andersen whose telephone number is (571) 272-8024. The examiner can normally be reached on M-F 8AM-4:30PM EST.

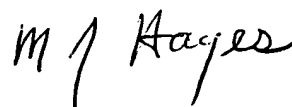
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hayes can be reached on (571) 272-4959. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

M. Thomas Andersen

November 20, 2006

A handwritten signature in black ink, appearing to read "M J Hayes".

MICHAEL J. HAYES
SUPERVISORY PATENT EXAMINER